

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ROANOKE DIVISION

TERESA M. BAILEY, <u>et al.</u> ,)	
Plaintiffs)	
)	
v.)	Case No: 7:20-cv-622
)	
ETHICON, INC., <u>et al.</u> ,)	By: Michael F. Urbanski
Defendants.)	Chief United States District Judge

MEMORANDUM OPINION

This matter is before the court on defendants Ethicon, Inc., Ethicon, LLC, and Johnson & Johnson's (collectively, "Ethicon") motion for summary judgment under Rule 56(a) of the Federal Rules of Civil Procedure. ECF No. 35. Plaintiff Teresa Bailey's counsel also filed a motion to withdraw as attorney, ECF No. 66. For the reasons discussed below, the court will **GRANT** Ethicon's motion for summary judgment in its entirety. Because summary judgment will be granted, Bailey's counsel's motion to withdraw will be **DENIED as moot**.

I.

Teresa Bailey is one of many individuals who filed suit against Ethicon for injuries suffered after being treated with Ethicon's pelvic mesh implant, TVT-O.¹ Bailey lives in Virginia and received her surgery on March 5, 2008, at Carilion New River Valley Medical Center ("Carilion") in Radford, Virginia.² Short Form Compl., ECF No. 1, at 1, 4. The physician who performed her procedure was Weldon Shaffer, III, M.D. Id. at 4. The purpose of the surgery was to treat Bailey's pelvic relaxation and stress urinary incontinence and related

¹ Both the TVT and TVT-O have been the subject of much litigation. In this case, Bailey received the TVT-O.

² As such, Virginia law applies to this case.

symptoms. Pl. Fact Sheet, ECF No. 35-1, at 4. Upon the recommendation of Dr. Shaffer, Bailey underwent a TVT-O mesh implant surgery. Bailey testified that she only relied on Dr. Shaffer's advice when deciding whether to pursue the surgery. Bailey Dep., ECF No. 37-2, at 121.

Dr. Shaffer testified that he was trained by Ethicon in Celebration, Florida, on several occasions regarding the proper use of TVT implants. Shaffer Dep., ECF No. 37-1, at 14-15, 18. He was also trained by an Ethicon doctor located at Carilion, Tamara Howell, on how to perform TVT-O procedures and had to perform a certain number of procedures under her direct supervision before being qualified to do the procedure on his own. Id. at 17-18. Dr. Shaffer further testified that potential risks and complications of the device, such as vaginal perforation, urethral injuries and erosion, mesh protrusion, infection, and device failure, were provided to him by Ethicon. Id. at 17. However, Dr. Shaffer already knew of these complications for both TVT and TVT-O. Id. Despite knowing these potential risks, Dr. Shaffer found the TVT-O to have good outcomes in his patients and generally found the implant to be safe. Id. at 21. Dr. Shaffer stands by his decision to treat Bailey with the TVT-O implant. Id. at 50.

To address potential TVT-O implant complications, Ethicon provided Instructions for Use ("IFU") and patient brochures to physicians. Id. at 33-34. While Dr. Shaffer referenced these materials, he did not solely rely on them when recommending mesh implants for patients. Id. at 31-32. Dr. Shaffer also said that it was his standard procedure to go over surgical risks and complications with his patients. Id. However, Bailey alleges that she does not remember receiving any brochures or pamphlets from Ethicon, but one could have been given

to her by Dr. Shaffer. Bailey Dep., at 106. Since 2010, Bailey has complained of suffering from various side effects of the surgery. Pl. Fact Sheet at 5. However, Bailey was unaware of the connection between her symptoms and the TVT-O implant surgery until 2012. Tr. of Apr. 19, 2021 Hr'g, at 18.

On March 7, 2013, Bailey brought the present action as a part of a Multi-District Litigation ("MDL"), alleging negligence (Count I); strict liability – manufacturing defect (Count II); strict liability – failure to warn (Count III); strict liability – defective product (Count IV); strict liability – design defect (Count V); common law fraud (Count VI); fraudulent concealment (Count VII); constructive fraud (Count VIII); negligent misrepresentation (Count IX); negligent infliction of emotional distress (Count X); breach of express warranty (Count XI); breach of implied warranty (Count XII); violation of consumer protection laws (Count XIII); gross negligence (Count XIV); unjust enrichment (Count XV); loss of consortium (Count XVI); punitive damages (Count XVII); and discovery rule and tolling (Count XVIII).³ While in MDL, Ethicon filed for summary judgment. Counsel for Bailey also filed to withdraw from this case. While Ethicon does not oppose counsel's withdrawal, Ethicon requests that the court rule on summary judgment before ruling on the motion to withdraw in order to prevent undue delay. ECF No. 67. These motions were not addressed in MDL, and the case was transferred to the Western District of Virginia on October 23, 2020.

Ethicon asserts that the Baileys' claims are barred by Virginia's statute of limitations. ECF No. 36. Ethicon further contends that even if Bailey's fraud claims are timely, they fail

³ A number of these claims, such as those alleging strict liability, are not recognized in Virginia. Because the court finds this case to be barred under Virginia law by the statute of limitations, the court need not address the substantive viability of plaintiff's strict liability claims.

because Bailey did not rely on any Ethicon documents to inform her decision about undergoing the implant surgery. Id. Bailey opposes. ECF No. 37. The court heard argument on April 19, 2021, and the matters are ripe for resolution.

II.

Under Rule 56(a), the court must “grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a); Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986); Glynn v. EDO Corp., 710 F.3d 209, 213 (4th Cir. 2013). When making this determination, the court should consider “the pleadings, depositions, answers to interrogatories, and admissions on file, together with . . . [any] affidavits” filed by the parties. Celotex, 477 U.S. at 322. Whether a fact is material depends on the relevant substantive law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). “Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted.” Id. (citation omitted). The moving party bears the initial burden of demonstrating the absence of a genuine issue of material fact. Celotex, 477 U.S. at 323. If that burden has been met, the non-moving party must then come forward and establish the specific material facts in dispute to survive summary judgment. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586–87 (1986).

In determining whether a genuine issue of material fact exists, the court views the facts and draws all reasonable inferences in the light most favorable to the non-moving party. Glynn, 710 F.3d at 213 (citing Bonds v. Leavitt, 629 F.3d 369, 380 (4th Cir. 2011)). Indeed, “[i]t is an ‘axiom that in ruling on a motion for summary judgment, the evidence of the

nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor.” McAirlaids, Inc. v. Kimberly–Clark Corp., 756 F.3d 307, 310 (4th Cir. 2014) (internal alteration omitted) (citing Tolan v. Cotton, 134 S. Ct. 1861, 1863 (2014) (per curiam)). Moreover, “[c]redibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge.” Anderson, 477 U.S. at 255.

The non-moving party must, however, “set forth specific facts that go beyond the ‘mere existence of a scintilla of evidence.’” Glynn, 710 F.3d at 213 (quoting Anderson, 477 U.S. at 252). The non-moving party must show that “there is sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party.” Res. Bankshares Corp. v. St. Paul Mercury Ins. Co., 407 F.3d 631, 635 (4th Cir. 2005) (quoting Anderson, 477 U.S. at 249). “In other words, to grant summary judgment the [c]ourt must determine that no reasonable jury could find for the nonmoving party on the evidence before it.” Moss v. Parks Corp., 985 F.2d 736, 738 (4th Cir. 1993) (quoting Perini Corp. v. Perini Constr., Inc., 915 F.2d 121, 124 (4th Cir. 1990)). Even when facts are not in dispute, the court cannot grant summary judgment unless there is “no genuine issue as to the inferences to be drawn from” those facts. World-Wide Rights Ltd. P’ship v. Combe Inc., 955 F.2d 242, 244 (4th Cir. 1992).

III.

Broadly, there are two categories of claims in this case: non-fraud and fraud claims.⁴ Ethicon argues that both categories of claims are time-barred by the two-year personal injury statute of limitations as her claims accrued at the time of her surgery. Bailey opposes, asserting at argument that it is fundamentally unfair for the statute of limitations to prevent her from

⁴ Non-fraud claims are Counts I – V and X – XV. Fraud claims are Counts VI – IX.

bringing a viable claim even when she was not, nor could not, have been aware of any problems associated with her TVT-O implant.⁵ While Bailey concedes there is no case law to support her assertion, she notes that Virginia’s accrual statute, Va. Code § 8.01-249, was subsequently amended to help ameliorate the hardship of the running of this statute of limitations. As such, Bailey argues that this amendment should be retroactively applied to her claims. Moreover, Bailey argues that her fraud claims should be decided on their merits because under the discovery rule the claims are timely.

A. Statute of Limitations as to Non-Fraud Claims

As to the non-fraud claims, Bailey is barred from recovery because the two-year personal injury statute of limitations ran two years after her surgery, in 2010. Virginia law requires personal injury claims be filed “within two years after cause of action accrues” regardless of the theory of recovery. Va. Code Ann. § 8.01-243.A; Adams v. Am. Optical Corp., 979 F.3d 248, 255 (4th Cir. 2020). The date of accrual is “the date the injury is sustained,” not when the damage is discovered. Va. Code Ann. § 8.01-230; Kerns v. Wells Fargo Bank, N.A., 296 Va. 146, 155, 818 S.E.2d 779, 782-83 (2018). Specifically, for products liability cases involving medical devices, the date the injury is sustained is the date of implantation regardless of whether more significant injuries are later sustained. Smith v. Danek Med., Inc., 47 F. Supp. 2d 698, 701 (W.D. Va. 1998) (“[A]llegations of design defect and unreasonable dangerousness necessarily fix the accrual of the cause of action at the time of implantation, even though more substantial injury may have occurred later”); see also

⁵ On brief, Bailey did not address Ethicon’s statute of limitations argument.

Neal v. Stryker Corp., No. 1:11-cv-62, 2011 WL 841509, at *1 (E.D. Va. Mar. 8, 2011) (holding the same).

On July 1, 2016, Va. Code § 8.01-249 was amended, stating that products liability claims involving medical devices begin accruing when plaintiff “knew or should have known of the injury and its causal connection to the device.” Va. Code § 8.01-249(9). Bailey did not see a doctor until 2012 to confirm that her complications were attributable to her TVT-O implant, Tr. of Apr. 19, 2021 Hr’g, at 18, and this case was filed on March 7, 2013. As such, Bailey contends that because this case was pending at the time the statute was amended, she should “have the ability to take advantage of those statutory changes[,]” specifically where the amended statute directly bears on the issues in this case. Tr. of Apr. 19, 2021 Hr’g, at 19-20. This argument is foreclosed by Virginia law.

The Virginia Supreme Court has held that barred claims cannot be revived by retroactive application of amended statute of limitations as a matter of due process. Starnes v. Cayouette, 244 Va. 202, 207, 419 S.E.2d 669, 672 (1992). In Starnes, the plaintiff, Marjorie Starnes, was an adult survivor of child abuse perpetrated by a family friend, Robert Cayouette. Starnes’s abuse began when she was five years old and lasted until 1978, when she was fourteen years old. She turned 18 years old, the age of majority, in 1982. Cayouette constantly threatened Starnes to keep the abuse secret, resulting in Starnes becoming fearful and suffering from emotional harms “[including] eating disorders, sleep disturbances, depression and anxiety attacks.” Starnes first became aware of the connection between her sexual abuse and the above-mentioned harms from her psychologist in 1990.

In 1991, Starnes brought various claims against Cayouette related to her childhood sexual abuse. Citing the two-year statute of limitations for personal injury actions, Cayouette asserted that Starnes's claims were barred because the statute of limitations ran in 1984. In response, Starnes argued that under a recent amendment to Va. Code § 8.01-249(6), effective July 1, 1991, her claims were timely because she first learned of the connection between her claims and the abuse one year prior to filing her suit. In relevant part, the amendment to the accrual statute provided:

In actions for injury to the person, whatever the theory of recovery, resulting from sexual abuse occurring during the infancy or incompetency of the person, [the cause of action shall be deemed to accrue] when the fact of the injury and its causal connection to the sexual abuse is first communicated to the person by a licensed . . . psychologist.

Va. Code. § 8.01-249(6).

Because the amendment to the accrual statute did not occur until after the statute of limitations on Starnes's claims had run, the City of Hampton Circuit Court dismissed Starnes's claims. The Virginia Supreme Court affirmed, holding that while the legislature may amend statute of limitations to apply retroactively, this retroactivity cannot infringe upon defendants' vested due process rights. Quoting from its 1903 decision in Kesterson v. Hill, 101 Va. 739, 743-44, 45 S.E. 288, 289 (1903), the Virginia Supreme Court held:

[T]he right to set up the bar of a statute of limitations as a defence to a cause of action after the statute has run is a vested right, and cannot be taken away by legislation . . . and . . . it is immaterial whether the action is for the recovery of real or personal property, or for the recovery of a money demand, or for the recovery of damages for a tort.

Accordingly, the court ruled that the statute of limitations for Starnes's claims began to run in 1982 and ended in 1984.⁶ As such, even retroactive application of a statute cannot revive a claim that is already barred. See Parris v. Appalachian Power Co., 343 S.E.2d 455, 461 (Va. Ct. App. 1986) (“[O]nce the limitations period has run, any subsequent amendments to that period generally would have no effect on the parties’ procedural rights.”); Lewis v. Gupta, 54 F. Supp. 2d 611, 617 (E.D. Va. 1999) (refusing to retroactively apply tolling statute that went into effect after statute of limitations had expired.).

The Fourth Circuit recently affirmed the Starnes rationale. See Newhouse v. Ethicon, Inc., No. 2:17-cv-02735, 2020 WL 609622 (S.D.W Va. Feb. 7, 2020), aff’d, No. 20-1238, 2020 WL 5049055 (4th Cir. Aug. 27, 2020). Applying Virginia law and citing Starnes, the Newhouse court found that plaintiff’s claims were time barred. The district court granted summary judgment and held that because the statute of limitations for plaintiff’s personal injury claims had run prior to the July 1, 2016 amendment to Va. Code § 8.01-249, the claims could not be retroactively revived by the amendment as a matter of due process. Newhouse, 2020 WL 609622, at *4 n.3.

The same reasoning applies here. Bailey’s claims are time barred and cannot be revived through retroactively applying the amended § 8.01-249. Bailey’s TVT-O implant procedure occurred on March 5, 2008. She first experienced symptoms in 2010. This case was filed on March 7, 2013. Plainly, more than two years elapsed following the 2008 implant date. Even if

⁶ Although it does not diminish the precedential value of the holding in Starnes to the facts of this case, the Constitution of Virginia was amended in 1994 to supersede the result in Starnes, and allowed the General Assembly to provide for retroactive application of a change in the accrual date of the statute of limitations for intentional torts committed by a natural person against minors.

the statute of limitations did not accrue until Bailey first became symptomatic, her claim would still be time barred. Because the statute of limitations for Bailey's claims had run before the General Assembly in 2016 changed the accrual date for medical device cases to include a discovery rule, the later amended accrual statute does not apply to Bailey's claims as a matter of due process. Accordingly, summary judgment is required as to Bailey's non-fraud claims.

B. Statute of Limitations as to Fraud Claims

As to Bailey's fraud claims, Ethicon asserts they are merely repackaged personal injury claims. Therefore, Ethicon argues that like the non-fraud claims, Bailey's fraud claims should be time-barred under the two-year personal injury statute of limitations. Bailey argues that her fraud claims are subject to the discovery rule statute of limitations and are therefore timely. The court agrees.

Unlike the personal injury statute of limitations, the statute of limitations for fraud claims does not begin until the damage is or should have been discovered, known as the discovery rule. See Va. Code Ann. § 8.01-249(1). However, it is settled law that "the applicability of the statute of limitations is governed by the object of the litigation and the substance of the complaint, not the form in which the litigation is filed." Kappa Sigma Fraternity, Inc. v. Kappa Sigma Fraternity, 266 Va. 455, 465, 587 S.E.2d 701, 707 (2003); Bd. of Supervisors v. Thompson Assocs., 240 Va. 133, 139, 393 S.E.2d 201, 204 (1990); Friedman v. Peoples Serv. Drug Stores, Inc., 208 Va. 700, 703, 160 S.E.2d 563, 565 (1968).

While this proposition holds true, the cited authorities reveal that this principle applies to declaratory judgment suits. See Kappa Sigma Fraternity, 266 Va. at 465, 587 S.E.2d at 707 (holding that in a declaratory judgment suit, the object of the litigation controls the statute of

limitations rather than the litigation's form); Bd. of Supervisors, 240 Va. at 139, 393 S.E.2d at 204 (same); Friedman, 208 Va. at 703, 160 S.E.2d at 565 (same). As such, the court is unwilling to extend this rationale to limit Bailey's fraud claims in this case.

Bailey's surgery occurred in 2008, and a doctor first informed her of the nexus between her symptoms and the implant in 2012. As such, the statute of limitations was tolled under the discovery rule between 2008 and 2012. Only one year passed between the time Bailey became aware of her implant complications and initiation of this suit. Accordingly, Bailey's March 7, 2013 suit is timely as to her fraud claims. Having determined Bailey's fraud claims are timely, the court must now consider the merits of the fraud claims.

C. Fraud Claims Fail Due to Lack of Reliance

Ethicon argues that Bailey can prove neither actual nor constructive fraud. To prove actual fraud, a plaintiff must show "(1) false representation, (2) of a material fact, (3) made intentionally and knowingly, (4) with the intent to mislead, (5) reliance by the party misled, and (6) resulting damage to the party misled." Cohn v. Knowledge Connections, Inc., 266 Va. 362, 368, 585 S.E.2d 578, 581 (2003). To prove constructive fraud, the plaintiff need not prove intent to mislead. Id. at 369. Rather, the plaintiff must show the "misrepresentation forming the basis of the claim caused damage to the one relying on it." Id.

Specifically, Ethicon asserts that because Bailey did not rely on any document from Ethicon to inform her decision to have the implant surgery, no fraud occurred. ECF No. 36 at 16. Bailey refutes, saying that because Ethicon negligently misrepresented the potential risks of TVT-O surgery to Dr. Shaffer by providing deficient warnings and inadequate training,

Ethicon affirmatively misrepresented the medical device's safety. ECF No. 37 at 9. Bailey's argument is foreclosed by Virginia law.

In Scholl v. Ethicon, Inc., No. 2:12-cv-00738, 2016 WL 7242552 (S.D.W. Va. Dec. 14, 2016), a West Virginia District Court considered the issue of fraud by third-party reliance. Applying Virginia law, the court held:

Virginia law requires proof of reliance by the injured party, as opposed to reliance by a third party, in order to maintain an action for fraud. Richmond Metro. Auth. v. McDevitt St. Bovis, Inc., 256 Va. 553, 557, 507 S.E.2d 344, 346 (1998) (noting that fraud claims require "reliance by the party misled"). Establishing the element of reliance by the injured party can be "problematic" in the medical device context because any alleged misrepresentations are typically made to the prescribing doctor or other learned intermediary. Robert E. Draim, Va. Practice Series Prods. Liab. § 6:7. Mrs. Scholl never interacted with any representative of Ethicon, nor did she read or review any materials created by Ethicon. The court has not found any evidence that Mrs. Scholl "relied" on a misrepresentation by Ethicon, so this element cannot be met and must be dismissed as a matter of law.

Scholl, 2016 WL 7242552, at *4.

The issue of fraud by third-party reliance was again discussed in Dickson v. Ethicon Inc., No. 2:15-cv-2800, 2020 WL 1492883 (S.D.W. Va. Mar. 27, 2020). In Dickson, plaintiff Mary Dickson sued Ethicon, on behalf of her mother, alleging four counts of fraud. Dickson testified that her mother did not see or rely on any brochures, pamphlets, documents, or materials from Ethicon when considering surgery. Nor did Dickson's mother interact with any Ethicon representatives. Dickson argued that because Ethicon allegedly made fraudulent representations to her mother's doctor, that was sufficient to prove fraud. Applying Virginia law and citing Scholl, the district court disagreed, holding that "[m]erely showing that

[Dickson's mother's] physician relied on the defendants' alleged misrepresentations cannot establish the essential element of reliance for fraud, fraudulent concealment, and constructive fraud." Dickson, 2020 WL 1492883, at *5.

The rationale of Scholl and Dickson applies here. Bailey testified that she did not rely on any materials from Ethicon in making her decision to proceed with the TVT-O procedure. Even if Dr. Shaffer showed Bailey an Ethicon brochure disclosing possible surgical complications, Bailey did not rely on it. Nor did Bailey interact with an Ethicon representative. Bailey stated that she solely relied on the advice of Dr. Shaffer to inform her surgical decision making. As such, Bailey cannot rely on Ethicon's alleged misrepresentations to Dr. Shaffer to prove fraud. Bailey presents no evidence to prove that she relied on anything from Ethicon as required under Virginia law. Because Bailey fails to prove that Ethicon made a misrepresentation to her, summary judgment must be granted as to Bailey's fraud claims.⁷

IV.

For these reasons, the court finds that there is no genuine dispute of material fact as to the applicability of the two-year personal injury statute of limitations to the non-fraud claims Bailey brought against Ethicon. Moreover, Bailey relied on no document or information from Ethicon when deciding to proceed with her TVT-O surgery. As such, the court **GRANTS** Ethicon's motion for summary judgment in its entirety. Because the court grants Ethicon's

⁷ Because Bailey's constructive fraud claim fails, she cannot bring a separate negligent misrepresentation claim. See Dickson, 2020 WL 1492883, at *5 ("A plaintiff's inability to establish constructive fraud thus precludes her from recovering for negligent misrepresentation."). As such, summary judgment must be granted as to Count IX.

motion for summary judgment, Bailey's counsel's motion to withdraw as attorney is
DENIED as moot.

An appropriate order will be entered.

Entered: June 7, 2021

A handwritten signature in blue ink, appearing to read 'M. Urbanski', is positioned to the left of the judge's name and title.

Michael F. Urbanski
Chief U.S. District Judge
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Michael F. Urbanski
Chief United States District Judge